

## PATENT COOPERATION TREATY


## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 15 JUL 2005

WIPO

Applicant's or agent's file reference 6395-67675-01	<b>FOR FURTHER ACTION</b> See Form PCT/PEA/416	
International application No. PCT/US2004/009767	International filing date (day/month/year) 26.03.2004	Priority date (day/month/year) 28.03.2003
International Patent Classification (IPC) or national classification and IPC C07K14/16		
Applicant THE GOVERNMENT OF THE UNITED STATES ...et al.		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand  27.10.2004	Date of completion of this report  04.07.2005	
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Telephone No. +49 89 2399-7877  Young, C.	



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/US2004/009767

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-40 as originally filed

**Sequence listings part of the description, Pages**

1-39 as originally filed

**Claims, Numbers**

1-26 as originally filed

**Drawings, Sheets**

1-7 as originally filed

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	5,6,7
	No: Claims	1-4,8-26
Inventive step (IS)	Yes: Claims	
	No: Claims	5,6,7
Industrial applicability (IA)	Yes: Claims	1-26
	No: Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

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**Supplemental Box relating to Sequence Listing**

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**Continuation of Box I, item 2:**

1. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this report has been established on the basis of:
  - a. type of material:
    - ☒ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☒ in written format
    - ☒ in computer readable form
  - c. time of filing/furnishing:
    - ☒ contained in the international application as filed
    - ☐ filed together with the international application in computer readable form
    - ☒ furnished subsequently to this Authority for the purposes of search and/or examination
    - ☒ received by this Authority as an amendment on
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional observations, if necessary:

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents/:

- D1: SINGH RANA A K ET AL: "Generation of genome-wide CD8 T cell responses in HLA-A0201 transgenic mice by an HIV-1 ubiquitin expression library immunization vaccine." JOURNAL OF IMMUNOLOGY, vol. 168, no. 1, 1 January 2002 (2002-01-01), pages 379-391, XP002308576 ISSN: 0022-1767
- D2: LACASSE R ET AL: "Fusion-competent vaccines: Broad neutralization of primary isolates of HIV" SCIENCE, AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE,, US, vol. 283, no. 5400, 15 January 1999 (1999-01-15), pages 357-362, XP002120812 ISSN: 0036-8075
- D3: LU: "HIV-1 Gag DNA Vaccine Chimera with Expression and Adjuvant Properties of the Lysosomal-Associated Membrane Protein (LAMP) and Dendritic Cell Multi-Lectin Receptor (DC-MLR) in an AAV-ITR Plasmid Vector" AIDS VACCINE CONFERENCE ABSTRACT, [Online] 7 September 2001 (2001-09-07), XP002308577 Retrieved from the Internet: URL:<http://63.84.172.40/Posters/312.1.pdf> [retrieved on 2004-12-01]
- D4: EP-A-1 130 089 (DEUTSCHES KREBSFORSCH) 5 September 2001 (2001-09-05)
- D5: OWEN SHERRY M ET AL: "Susceptibility of diverse primary HIV isolates with varying co-receptor specificity's to CXCR4 antagonistic compounds" JOURNAL OF MEDICAL VIROLOGY, vol. 68, no. 2, October 2002 (2002-10), pages 147-155, XP002308578 ISSN: 0146-6615

**Novelty, Article 33 (2) PCT**

D1 discloses a recombinant polyepitope polypeptide comprising a plurality of amino acid segments from one or more HIV proteins comprising a spacer and being linked to a targeting signal, whereby the targeting signal is ubiquitin. As a consequence claims 1-4 are anticipated by this disclosure.

Claim 8 attempts to further define the claimed polypeptide by referring to the nature of

the epitopes. These epitopes are inherently disclosed in the peptide vaccines of D1 and do not in any way contribute to novelty. Likewise the vectors, hosts, compositions of D1 and the methods described or alluded to using said peptides to treat HIV anticipate claims 9-26 of the present application.

Thus claims 1-4,8-26 are not in conformance with Article 33 (2) PCT.

As can be inferred from the above assessment claims 5 and 6 are novel over D1 as they relate to the use of co-receptors in particular CCR5. Moreover the exact sequence of the spacer element is not defined in D1 therefore formally novelty is recognized for claim 7 over D1-D5.

### **Inventive step, Article 33 (3) PCT**

D4 and D5 disclose the use of chemokine co-receptors in the treatment of HIV. In particular D4 describes the use of a fusion of co-receptors with defective HIV envelop as a useful vaccine. Claims 5 and 6 relate to the physical fusion of the co-receptor encoded by a corresponding DNA segment. In essence the skilled person would combine the teachings of D1 with that of D4 and derive the subject-matter of claims 5 and 6 without the use of inventive skill. In addition claim 7 which defines a spacer element between sequences as having a particular amino acid sequence is a mere arbitrary feature which can not contribute to the inventive character of the claimed scope.

In conclusion claims 5-7 are not regarded as being inventive and thus contravene Article 33 (3) PCT.

It is of interest to the Applicant and also the general public that D3 discloses the use of lysosomal targeting signals for HIV peptide vaccines prior to the present application. It is considered by this authority that this is a trivial option available to the skilled person at the time of filing the present application. This may become relevant if the applicant seeks to overcome the above objections by restricting to a lysosomal targeting system.